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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/812,802	03/20/2001	Kazuya Kawasaki	JG-TT-5053 / 500568.20026	1201
26418	7590	09/15/2005	EXAMINER	
REED SMITH, LLP ATTN: PATENT RECORDS DEPARTMENT 599 LEXINGTON AVENUE, 29TH FLOOR NEW YORK, NY 10022-7650			ALEXANDER, LYLE	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 09/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/812,802	<b>Applicant(s)</b> KAWASAKI ET AL.	
	<b>Examiner</b> Lyle A. Alexander	<b>Art Unit</b> 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 4-8 and 10-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-8 and 10-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1743

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 4-8, 10 and 13-19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Amano et al. (USP 5,508,173).

Amano et al. teach a multilayer test strip comprising a water impermeable and light transmissive hydrophilic support, a reagent layer and a porous spreading layer. Column 3 lines 45+ through column 4 teach the support may be made of PET which is identical to the example in the original that teaches this layer to be made of the same polymer. The reagent layer is taught in column 4 as being a hydrophilic polymer such as gelatin with binders of PVA, PET or cellulose acetate that have an approximate thickness between 3 and 50 microns in the dry state which has been read on the claimed polymer. The spreading layer is taught as having a void volume of 3 to 15 micro liters per square centimeter and has been read on the claimed mesh layer having an aperture diameter of between 0.05-7.5mm. Additionally, it is notoriously well known in the art the taught "broad cloth" has a porosity of 2.5-500 microns which has been read on the claimed range (e.g. see Kitajima (USP 4,337,222) cited below that teaches the porosity of broad cloth in column 3 lines 45-53). Column 6 teaches examples of the spreading layer. The structure supporting the layers has been read on the claimed "... water impermeable frame body with defines a compartment ...". In light of the 35 USC 112 issues above, it is difficult for the Office to known what is intended by the claimed

Art Unit: 1743

"punching sheet" and this has been interpreted as a sheet with circular holes which is indistinguishable from Amano et al.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amano et al. (USP 5,508,173).

Sée Amano et al. supra.

Amano et al. is silent to the mesh in the shape of tetragon or hexagon.

The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable is one that has well known and predictable results. The shape of a mesh is a result effective variable having the expected result of permitting the transfer of material. The shape may be dependent upon the material used for the mesh and would have been expected to permit transfer of the material.

It would have been within the skill of the art to modify Amano et al. and use a material having meshes in the shape of a tetragon or a hexagon as optimization of a result effective to gain the well known and expected advantages of permitting fluid transfer.

The court decided In re Dailey (149 USPQ 47) " the configuration of the container

is a mere matter of choice not significant" to define over art that has the same elements" but a different shape. Hexagonal and tetragon shapes have the advantages of minimizing the void volume between adjacent plates by the fact they fit together well. It would have been within the skill of the art to modify Amano et al. and use a tetragon or hexagon shape for the plate to minimize the void volume between interconnecting plates because the configuration of the plate is " a mere matter of choice".

### ***Response to Arguments***

Applicant's arguments filed 6/29/05 have been fully considered but they are not persuasive.

Applicants' argue Amano et al. does not teach a mesh layer with the claimed porosity. The Office maintains it is notoriously well known in the art that broad cloth meets the claimed porosity requirements as taught by Kitajima (USP 4,337,222) in column 3 lines 45-53).

The Office will considered the non-USP documents if Applicants' cited them on a PTOL-1449.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kitajima (USP 4,337,222) teaches the porosity of broad cloth in column 3 lines 45-53 as 2.5-500 microns.

Art Unit: 1743

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

Lyle A Alexander  
Primary Examiner  
Art Unit 1743

